REMARKS

In view of the above amendments and following remarks, reconsideration and further examination are requested.

Claims 28-33 have been cancelled and claims 34-47 have been added. New claims 34-47 have been drafted taking into account the 35 U.S.C. 112, second paragraph, issues raised by the Examiner, are believed to be free of these issues, and are otherwise believed to be in compliance with 35 U.S.C. 112, second paragraph.

Claims 28-33 were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DeLaCroix et al., and claims 28-33 were rejected under 35 U.S.C. 102(b) as being anticipated by Kuo (EP '084). These rejections are respectfully traversed, and DeLaCroix et al. and EP '084 are not applicable with regard to the currently pending claims for the following reasons.

With regard to the rejections based on DeLaCroix et al., each of the independent claims now more clearly defines a correction step which is not taught or suggested by DeLaCroix et al. Accordingly, claims 34-47 are not anticipated by nor rendered obvious over DeLaCroix et al. Thus, claims 34-47 are allowable over this reference.

An important feature of the instant invention is that the amount of the marker reagent that has been eluted from the first part of the development portion (independent claims 34 and 41), or the amount of the marker reagent that has not been eluted from the first part of the development portion (independent claims 38 and 45), is measured before the marker reagent eluted by the inspection target solution reaches and reacts with the immobilized reagent in the second part of the development portion. The significance of performing such measurement at this time is explained on pages 15-16 of the original specification, and this measurement is represented by reference numeral "6" while the second part of the development portion is represented by reference numeral "4". In other words, this measurement is performed before occurrence of any "reaction" including the immobilized reagent.

Thus, a main difference between the present invention and Kuo is that a signal for correction of Kuo is obtained on the basis of a "reaction", whereas a signal for correction of the instant is **not** obtained on the basis of any "reaction". Specifically, in Kuo the second zone (area 4) is read after the marker reagent (labeled binding partner) has been eluted thereinto by the inspection target

solution (fluid sample). Thus, contrary to the instant invention, a measurement in Kuo corresponding to the measurement of the instant invention as described in the preceding paragraph is performed after the marker reagent has reached and reacted with the immobilized reagent in the second zone.

This second zone (area 4) is referred to by Kuo as a "capture zone" and area 5 is referred to as a "detection zone". A relationship between these zones is described on page 4, paragraph [0013], as follows.

> Since the capture and detection zones' reflectance changes opposite to one another, i.e. the greater the signal from the capture zone the less the signal from the detection zone, the use of multiple capture and/or detection bands is designed to alter this range of reflectance values. The mechanism by which analyte concentration changes the band's reflectance is a function of the chemistry of a particular assay. For sandwich assays, with increasing analyte concentration, the capture band reflectance increases and the detection band reflectance band reflectance decreases. For competitive assays, the capture band reflectance decreases and detection band reflectance increases with increasing amounts of analyte in the fluid test sample.

Thus, the detection zone (for obtaining an original measurement result) and the capture zone (for obtaining a correction value) are mutually influenced. In other words, while the analyte concentration in the fluid test sample is unknown, the amount of analyte captured in the detection zone changes depending on the analyte concentration, and with this change the amount of analyte captured in the capture zone changes.

However, in order to perform an accurate correction, it is fundamentally required that an independent and universal signal be used for the correction, which signal does not relate to the measurement system ("reaction") for measuring analyte which is to be measured. Otherwise, there is no significance in correcting the unknown analyte concentration, there arises deterioration in accurateness and precision, and the correction itself leads to deterioration.

In this regard, since the correction utilizing the above-described "reaction" disclosed in Kuo is affected by the influences of the reagent related to the "reaction", when a capture reaction is not caused, or a proper amount of analyte is not obtained due to deactivation of the reagent immobilized

in the capture zone, for some reason, an incorrect correction can be performed, and as a consequence, an incorrect measurement result will be given to the user. An incorrect measurement result given to the user could be fatal, because many users have insufficient knowledge with regard to measurement principles and reaction principles for diagnostic medicine for clinical use, especially for POCT (Point-of-Care-Testing) use.

The signal for correction in the present invention is an inherent and universal signal which is independent of any reaction. In the present invention, since "the eluted value" = "the marker reagent amount related to measurement", it is possible to perform accurate correction by detecting a marker reagent amount related to measurement, which is not affected by any "reaction" and is more universal.

Furthermore, because Kuo requires an immobilized reagent to obtain a signal for correction, a production process of a test strip is more complicated as compared to that of the instant invention, which complicated production process increases manufacturing and management costs. To the contrary, the present invention dose not require an immobilized reagent for determining an eluted amount, or non-eluted amount, of a marker reagent, whereby a low-cost device can be realized.

To clarify the aforementioned distinction between the instant invention and Kuo, each of independent claims 34 and 41 requires a first measurement step performed ***in an arbitrary position between the first and second parts of the development portion***. Independent claims 38 and 45 require that a second measurement step is also performed ***in an arbitrary position***. In Kuo, an analogous measurement step is not performed in an arbitrary position, but is rather performed at a set and definite position (i.e. area 4). Thus, claims 34, 38, 41 and 45 are not anticipated by Kuo, whereby claims 34-47 are allowable.

Additionally, independent claims 34 and 38 further require that ***the immobilized reagent is a reagent that can be specifically bonded to the measurement target.*** This further requirement is also believed to distinguish these claims from Kuo. In this regard, in Kuo the immobilized reagent in area 4 is to be bonded to the analyte, whereas area 5 contains a means for capturing the labeled specific binding partner which did not bind in area 4. Area 5 is not disclosed to include any reagent for binding to the analyte. Thus, area 4 of Kuo must be equated to the second part of the development portion as recited in claims 34 and 38, and area 5 cannot be equated to the second part, whereby Kuo fails to teach or suggest the first and second measurement steps as recited in claims 34

and 38. Thus, for this additional reason claims 34 and 38 are not anticipated by Kuo, whereby claims 34-40 are allowable.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early Notice of Allowance is earnestly solicited.

If after reviewing this Amendment, the Examiner believes that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the Applicants' undersigned representative by telephone to resolve such issues.

Respectfully submitted,

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